

DRUG DISCOVERY

FDA approved drugs – August 2013

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1. MIRVASO (BRIMONIDINE)

1.1. Company

Galderma Labs; Approved by August 2013

1.2. Treatment Area

Facial erythema of rosacea

1.3. General Information

Mirvaso is specifically indicated for the topical treatment of persistent (nontransient) erythema of rosacea in adults 18 years of age or older. It is supplied as a gel for topical administration. The recommended dose and administration of Mirvaso is as follows: a pea-size amount once daily to each of the five areas of the face: central forehead, chin, nose, each cheek. Mirvaso topical gel should be applied smoothly and evenly as a thin layer across the entire face avoiding the eyes and lips.

1.4. Mechanism of Action

Mirvaso (brimonidine) is a relatively selective alpha-2 adrenergic agonist. Topical application of Mirvaso gel may reduce erythema through direct vasoconstriction.

1.5. Side Effects

Adverse events associated with the use of Mirvaso includes: erythema, flushing, skin burning sensation, contact dermatitis

2. VALCHLOR (MECHLORETHAMINE) GEL

2.1. Company

Ceptaris Therapeutics; Approved by August 2013

2.2. Treatment Area

Stage IA/IB mycosisfungoides-type cutaneous T-cell lymphoma

2.3. General Information

Valchlor is specifically indicated for the topical treatment of Stage IA and IB mycosisfungoides-type cutaneous T-cell lymphoma in patients who have received prior skin-directed therapy. It is supplied as a gel for topical administration. The recommendation is to apply a thin film of Valchlor gel once daily to affected areas of the skin. Upon improvement, treatment with Valchlor can be restarted at a reduced frequency of once every 3 days. If reintroduction of treatment is tolerated for at least one week, the frequency of application can be increased to every other day for at least one week and then to once daily application if tolerated.

2.4. Mechanism of Action

Valchlor is a gel formulation of mechlorethamine, also known as nitrogen mustard, an alkylating agent which inhibits rapidly proliferating cells.

2.5. Side Effects

Adverse events associated with the use of Valchlor includes: dermatitis, pruritus, bacterial skin infection, skin ulceration or blistering, hyperpigmentation.

3. TIVICAY (DOLUTEGRAVIR)

3.1. Company

ViiV HealthCare; Approved by August 2013

3.2. Treatment Area

HIV-1 in adults and children over 12 years of age

3.3. General Information

Tivicay is specifically indicated in combination with other antiretroviral agents for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults and children aged 12 years and older and weighing at least 40 kg. It is supplied as a tablet for oral administration. The recommended dose is as follows:

3.4. Adults

Treatment-naïve or treatment-experienced INSTI-naïve: 50 mg once daily Treatment-naïve or treatment-experienced INSTI-naïve when coadministered with the following potent UGT1A/CYP3A inducers: efavirenz, fosamprenavir/ritonavir, tipranavir/ritonavir, or rifampin: 50 mg twice daily INSTI-experienced with certain INSTI-associated resistance substitutions or clinically suspected INSTI resistance: 50 mg twice daily

3.5. Pediatrics

Treatment-Naïve or Treatment-Experienced INSTI-Naïve: The recommended dose in pediatrics aged 12 years and older and weighing at least 40 kg is 50 mg administered orally once daily.

3.6. Mechanism of Action

Tivicay (dolutegravir) inhibits HIV integrase by binding to the integrase active site and blocking the strand transfer step of retroviral deoxyribonucleic acid (DNA) integration which is essential for the HIV replication cycle.

3.7. Side Effects

Adverse events associated with the use of Tivicay includes: insomnia, headache.

4. TROKENDI XR (TOPIRAMATE)

4.1. Company

Supernus Pharmaceuticals; Approved by August 2013

4.2. Treatment Area

Partial onset, tonic-clonic and Lennox-Gastaut Syndrome seizures

4.3. General Information

Trokendi XR is specifically indicated as initial monotherapy in patients 10 years of age and older with partial onset or primary generalized tonic-clonic seizures and adjunctive therapy in patients 6 years of age and older with partial onset or primary generalized tonic-clonic seizures. It is also indicated as adjunctive therapy in patients 6 years of age and older with seizures associated with Lennox-Gastaut syndrome. It is supplied as a capsule for oral administration. The recommended dose regimen is as follows:

4.4. Monotherapy Use

Adults and Pediatrics 10 Years and Older with Partial Onset or Primary Generalized TonicClonic Seizures: 400 mg orally once daily. Titrate Trokendi XR according to the following schedule:

Week 1 50 mg once daily
Week 2 100 mg once daily
Week 3 150 mg once daily
Week 4 200 mg once daily
Week 5 300 mg once daily
Week 6 400 mg once daily

4.5. Adjunctive Therapy Use

Adults (17 Years of Age and Older) - Partial Onset Seizures, Primary Generalized Tonic-Clonic Seizures, or Lennox-Gastaut Syndrome: partial onset seizures or Lennox-Gastaut Syndrome - 200 mg to 400 mg orally once daily; primary generalized tonic-clonic seizures - 400 mg orally once daily. Initiate therapy at 25 mg to 50 mg once daily followed by titration to an effective dose in increments of 25 mg to 50mg every week. Pediatrics (Ages 6 years to 16 Years) - Partial Onset Seizures, Primary Generalized TonicClonic Seizures, or Lennox-Gastaut Syndrome: approximately 5 mg/kg to 9 mg/kg orally once daily. Begin titration at 25 mg once daily (based on a range of 1 mg/kg/day to 3 mg/kg/day) given nightly for the first week. Subsequently, increase the dosage at 1- or 2 week intervals by increments of 1 mg/kg to 3 mg/kg to achieve optimal clinical response.

4.6. Mechanism of Action

Trokendi XR is an extended release formulation of topiramate, an anticonvulsant. The precise mechanisms by which topiramate exerts its anticonvulsant effects are unknown; however, preclinical studies have revealed four properties that may contribute to topiramate's efficacy for epilepsy. Electrophysiological and biochemical evidence suggests that topiramate, at pharmacologically relevant concentrations, blocks voltage-dependent sodium channels, augments the activity of the neurotransmitter gamma-aminobutyrate at some subtypes of the GABA-A receptor, antagonizes the AMPA/kainate subtype of the glutamate receptor, and inhibits the carbonic anhydrase enzyme.

4.7. Side Effects

Adverse events associated with the use of Topamax XR includes: paraesthesia, anorexia, weight decrease, fatigue, dizziness, somnolence, nervousness, psychomotor slowing, difficulty with memory, difficulty with concentration/attention, cognitive problems, confusion, mood problems, fever, infection, flushing.